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**AkzoNobel**
Tomorrow's Answers Today

April 15, 2013

8EHQ-13-19063

US EPA Office of Pollution Prevention and Toxics
EPA East Building Room 6428
Attn: Section 8(e)
1201 Constitution Avenue, NW
Washington, DC 20004

**SUBJECT: TSCA 8(e) Notice**

8813000022 1

Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Surface Chemistry LLC, we are reporting the results of an acute inhalation study (single 4-hour, head-nose exposure) under Section 8(e) of TSCA. This toxicology study was performed by BASF in Germany on its product Lutensol FA 15 T, which was described as Amines, tallow alkyl, ethoxylated, CAS# 61791-26-2. Lutensol FA 15 T was tested as a liquid aerosol generated at 60°C/140°F. The study was performed using male and female Wistar rats and was performed in accordance with OECD Guideline 403. (Note: CAS# 61791-26-2 is considered a skin irritant. This should be kept in mind when reviewing the results of the acute inhalation study where the ethoxylated amine came into direct contact with the sensitive tissues of the lung.)

The test substance was administered as an aerosol that was produced by continuously pumping amounts of the test substance to a heated two-component atomizer at 60°C/140°F. The product as supplied was too viscous for an aerosol to be generated at ambient temperatures (communication from BASF). Therefore, to generate a respirable aerosol, the substance had to be heated to 60°C/140°F and atomized. Using compressed air, the aerosol was produced with the atomizer inside the exposure system. The following measured concentrations were tested: 0.27, 0.60, 2.3 and 5.7 mg/L (analytical concentration). Under the conditions of aerosol generation at 60°C/140°F, the results of cascade impactor measurements showed a particle size distribution with mass median aerodynamic diameters (MMADs) between 1.0 and 2.2 µm.

One of five males and three of five females died at 0.27 mg/L, as well as two of five males and two of five females at 0.60 mg/L. At 2.3 and 5.7 mg/L, all the male and female died. Lethality was observed after exposure on study day 0, on study day 1 - 4, 9, 10 or on study day 12.

The mean body weights of the male animals surviving the exposure period decreased during the first post exposure observation week but increased during the second week. The mean body weights of the female animals surviving the exposure period decreased throughout the study period. Clinical signs of toxicity in exposed animals included comprised visually accelerated respiration, gasping, respiration sounds, crust formation around the nose, apathy, squatting posture, reduced general state, piloerection and smeared fur.

Gross necropsy of the animals that died showed diffuse (dark)-red discoloration of all lung lobes: the surface of some part of the tissue was sunken. At the highest exposure level, findings were described as lung emphysema. Severe dilatation of the gastro intestinal tract filled with gaseous matter was observed. Histopathology of the lungs of one female animal showed distinct congestion, slight alveolar edema and a focal moderate suppurative necrotizing bronchopneumonia. The histopathological finding of a second female animal was similar to

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those described above but less severe.

Based on these results, under the unique exposure conditions of this study, the acute LC50 for male and female rats after liquid aerosol inhalation exposure of Lutensol FA 15 T heated to 60°C/140°F and atomized was estimated to be 0.473 mg/L (analytical concentration). As stated previously, the test substance had to be heated to 60°C/140°F in order to generate a respirable aerosol. However, to the best of our knowledge, under normal industrial use and processing, this product would not be heated to 60°C/140°F.

Please contact me at (312) 544-7061 if you have any questions regarding this letter.

Sincerely,

Louette Rausch

Louette Rausch
Expertise Leader Regulatory Affairs Americas
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From: (312) 544-7089
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**Section 8(e)**
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